PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 09 May 2000 (09.05.00)	
International application No. PCT/AU99/00762	**Applicant's or agent's file reference** 2214761/JMS
International filing date (day/month/year) 13 September 1999 (13.09.99)	**Priority date** (day/month/year) 14 September 1998 (14.09.98)
Applicant MATTHEWS, Barry, Ross et al	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   10 April 2000 (10.04.00)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Pascal Piriou
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

15

Applicant's or agent's file reference 2214761/jms	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU99/00762**	International filing date *(day/month/year)* 13 September 1999	Priority Date *(day/month/year)* 14 September 1998

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61K 31/74, 31/785, 31/795, A61P 39/04

Applicant

STARPHARMA LIMITED et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
10 April 2000	10 October 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **G.J. McNEICE** Telephone No. (02) 6283 2055

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU99/00762

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-12, 14	YES
	Claims 13	NO
Inventive step (IS)	Claims 1-12, 14	YES
	Claims 13	NO
Industrial applicability (IA)	Claims 1-14	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

Novelty (N) Claims 1-12, 14

Although
D1 "Metal Binding with modified dendrimer complexes" by Birnbaum et al, and
D2 "Polyamidoamine dendrimers: ..." by Diallo et al, disclose binding of toxic material using dendrimers having terminal groups of anionic or cationic - moieties, they do not disclose prophylactic or therapeutic inhibition in a patient.

D3 "Inhibition of the adherence of cholera toxin..." by Thompson et al discloses such therapeutic inhibition of toxic materials by dendrimers, but not dendrimers having terminal groups with anionic- or cationic - containing moieties bonded thereto.

Consequently the claims 1 to 12 and 14 are novel.

Claim 13

Claim 13 is directed to a composition suitable for prophylactic or therapeutic inhibition of a toxic material in a human or non-human animal, which composition includes an aqueous solution of the dendrimer. Both D1 and D2 disclose such compositions.

New citations:

D4. WO 95/34595 A (BIOMOLECULAR RESEARCH INSTITUTE LTD) 21 December 1995, page 3-6, 9-13

D5 Antisense & Nucleic Acid Drug Development 8:207-214 (1998) Mary Ann Liebert, Inc.., Attia, S.A "Interaction of Oligodeoxynucleotides with Mycobacteria: Implications for New Therapeutic Strategies"

D4 and D5 were cited in the ISR and IPE of PCT/AU 99/00763 by the present applicant. (your reference 2214579/jms)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V

D4 discloses prophylactic or therapeutic inhibition of microbial agents (in particular viruses) in a human or non-human animal, comprising administering to a patient a dendrimer having a plurality of terminal groups wherein at least one of said terminal groups has an anionic-or cationic - containing moiety bounded thereto. For example claim 9 and page 4 of the citation define the same compounds to be administered as does claim 10 of the present invention.

D5 discloses use of polycationic polyamidoamine dendrimers to treat bacterial infections. See page 208, column 2, lines 3 to 18 and pages 211 to 213.

Claim 13 is therefore not novel in the light of each of D1, D2, D4 and D5.

Inventive Step (IS) Claim 1-14

As for Novelty.

Industrial Applicability (IA)

Please note claims 1-12 are subject matters of rule 67.1 (methods of treatment of humans and animals) and as such do not require an international preliminary examination. However, because the subject matter does not contravene Australian law, these claims have been examined.